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|-----------------|-------------|----------------------|----------------------|------------------|
| 10/709,796      | 05/28/2004  | Michael A. Slivka    | 101896-251 (DEP5318) | 3795             |

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| EXAMINER |
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HOFFMAN, MARY C

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| ART UNIT | PAPER NUMBER |
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3733

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| NOTIFICATION DATE | DELIVERY MODE |
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08/19/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/709,796 | <b>Applicant(s)</b><br>SLIVKA ET AL. |  |
|                              | <b>Examiner</b><br>MARY HOFFMAN      | <b>Art Unit</b><br>3733              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-21, 23, 25 and 27-35 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 19, 20 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-18, 21, 23, 25, 27-31 and 33-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/03/2009 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-9, 12, 15, 18, 21, 23, and 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazel et al. (US Pub No. 2005/0171537) in view of Shih et al. (US 6,136,002).

Mazel et al. disclose a device (FIG. 1) for treating spinal deformities, comprising a spinal anchoring element (bottom part, ref. #6) adapted to seat first and second spinal fixation elements (ref. #4,5) and at a distance spaced apart from one another, the spinal anchoring element having a bore (ref. #15) extending therethrough; a fastening element

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(ref. #3) adapted to extend through the bore to mate the spinal anchoring element to bone; and a closure mechanism (ref. #7,29) mated to the spinal anchoring element to lock each of the first and second spinal fixation elements in a fixed position relative to the spinal anchoring element, and a set screw (ref. #28) having a head (top end) that is received within a bore of the closure mechanism that extends axially through the closure mechanism and aligns with the bore in the spinal anchoring element, and a threaded shaft adapted to threadably engage threads in the bore in the spinal anchoring element to mate the closure mechanism to the spinal anchoring element that directly engages the bore. The spinal anchoring element includes a first recess (ref. #8) adapted to receive a first spinal fixation element, and a second recess (ref. #9) spaced a distance apart from the first recess and adapted to receive a second spinal fixation element. The spinal anchoring element includes a central portion positioned between the first and second recesses and adapted to receive the fastening element for mating the anchoring element to bone. The central portion includes the bore extending therethrough. The closure mechanism includes a central portion (ref. #25) adapted to receive the set screw for mating the closure mechanism to the spinal anchoring element. The fastening element comprises a bone screw. The first recess is formed in a first end portion of the spinal anchoring element and the second recess is formed in a second, opposed end portion of the spinal anchoring element. Each end portion includes a superior surface and an inferior surface, the first and second recesses being formed in the superior surface. The closure mechanism includes a first end portion (ref. #10) adapted to lock a spinal fixation element within the first recess, and a second end

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portion (ref. #11) adapted to lock a spinal fixation element within the second recess. The device further comprising first and second spinal fixation elements (ref. #4, 5) adapted to be disposed between the spinal anchoring element and the closure mechanism. Each recess has a substantially concave shape.

Mazel et al. disclose the claimed invention except for the bore of the closure mechanism being tapered.

Shih et al. disclose a closure mechanism with a tapered bore as a suitable configuration for providing a bore that receives a setscrew with a corresponding head. The tapered configuration allows the setscrew to lie flush with the top of the closure mechanism and also provides an abutment surface for the head of the setscrew as the setscrew is inserted into the closure mechanism.

It would have been obvious at the time the invention was made to construct the device of Mazel et al. with a tapered bore (and corresponding head of the set screw) in view of Shih et al., since such would have been a functionally equivalent configuration for the purposes of securing a closure mechanism via a set screw.

Regarding claims 10-11, and 33, Mazel et al. disclose the claimed invention except for bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions.

Shih et al. disclose bone engaging members (spikes) extending distally from the inferior surface of each of the first and second end portions for gripping bone.

It would have been obvious at the time the invention was made to construct the fixation elements of Mazel et al. with bone engaging members (spikes) extending

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distally from the inferior surface of each of the first and second end portions in view of Shih et al. to grip bone.

Claims 16-17 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazel et al. (US Pub No. 2005/0171537) in view of Paul et al. (US 2004/0236327).

Mazel et al. disclose the claimed invention except for each spinal fixation element being flexible and being formed from a bioabsorbable material.

Paul et al. disclose spinal fixation element being flexible and being formed from a bioabsorbable material (paragraph [0097]) to provide an improved spinal fixation element.

It would have been obvious at the time the invention was made to construct the fixation elements of Mazel et al. being flexible and bioabsorbable in view of Paul et al. to provide a spinal improved fixation element.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that Mazel et al. does not disclose a set screw with a head. The examiner respectfully disagrees, since the "head" can be considered the top portion of set screw ref. #28. However, regarding Applicant's second argument, the examiner agrees that the threaded bore of the closure mechanism (ref. #29) is not threaded. However, the examiner maintains that it would have been obvious at the time the

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invention was made to construct the device of Mazel et al. with a tapered bore (and a corresponding head of the set screw) in view of Shih et al.

Applicant's amendments have overcome the previous rejection under Assaker and Gertzbein.

The rejections are deemed proper.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/  
Examiner, Art Unit 3733  
/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733